REMARKS

Applicants have amended claim 19 and have added new claims 37-48. No claim is cancelled. Accordingly, claims 19, 21-35, and 37-48 are pending.

Applicants respectfully submit that the amendment to claim 19 and the new claims are fully supported by the specification as originally filed and do not introduce any new matter. Support for the claim amendments is found throughout the specification, and specifically at, for example:

- page 4, lines 19-21, page 10, Table 3, and page 10, Table 4, for the amendment to claim 19.
- page 3, line 15 to page 4 line 5; page 4 lines 13-18, and page 10, Table 4, for new claims 37 and 39-48.
- page 10, Table 3 for new claim 38.

Applicants have reviewed the Examiner's objections and rejections set forth in the Office Action of October 22, 2007 and fully respond below.

Rejections under 35 U.S.C. § 103

Claims 19 and 21-35 stand rejected under 35 U.S.C. § 103 for allegedly being obvious over Lord et al. (USP 6,417,227), WO 00/85162, or Diehl (USP 4,113,881). The Examiner alleges that the use of cetylted fatty acids for the treatment of periodontal disease, as claimed herein, would have been obvious in view of references teaching the use of cetyl myristoleate for the treatment of arthritis. Applicants respectfully traverse.

Applicants respectfully submit that a thorough analysis of the obviousness question requires both the Applicants and the Examiner to apply the factual inquires enunciated by the U.S. Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966). The Graham factors include:

(A) Determining the scope and contents of the prior art;

(B) Ascertaining the differences between the prior art and the claims in issue;

(C) Resolving the level of ordinary skill in the pertinent art; and

(D) Evaluating evidence of secondary considerations.

Applicants respectfully submit that the Examiner has correctly determined the scope and contents of the cited prior art. The cited references disclose the use of cetyl myristoleate for the

treatment of arthritis. The difference between the teaching of the references and the claimed subject matter is that the references do not teach that cetyl myristoleate, or in fact any cetylated fatty acid, can be used for the treatment of periodontal disease.

Applicants further submit that the ordinary artisan is one with a degree of Doctor of Dental Surgery (DDS), who is a practicing dentist, and is familiar with the literature surrounding the treatment of periodontal disease and the standard of care and treatment for periodontal disease.

Applicants have submitted herewith a declaration by Dr. Thomas Van Dyke (the Van Dyke Declaration). Dr. Van Dyke, who is currently a professor at the Department of Periodontology and Oral Biology at Boston University Goldman School of Dental Medicine, is an expert in the field of treatment of periodontal disease. In his declaration, Dr. Van Dyke explains that the use of anti-inflammatory drugs in general for the treatment of periodontal disease were suggested some time ago, for example, in Heasman et al., J. Clin. Periodontol 1993; 20:457-464 (attached to the Van Dyke Declaration as *Exhibit A*, and is submitted separately in an Information Disclosure Statement), where the use of flurbiprofen was suggested to be effective. However, currently there are no anti-inflammatory drugs for that use on the market and the practitioners do not use anti-inflammatory drugs for the treatment of periodontal disease. See the Van Dyke Declaration, paragraphs 6 and 10. In fact, Dr. Van Dyke explains that:

> None of the currently available anti-inflammatory drugs are ever used for the treatment of periodontal disease. No dentist uses, or suggests the use of, anti-inflammatory medications for the treatment of periodontal disease. The standard of care for the treatment of periodontal disease, as suggested by the American Dental Association, and as taught throughout dental schools in the United States, does not include the use of anti-inflammatory drugs.

The Van Dyke Declaration, paragraph 10.

Dr. Van Dyke cites Pihlstrom et al., .Periodontol 2000, 2001, 25:37-58, which is attached to the Van Dyke Declaration as *Exhibit B*, and is submitted separately in an Information Disclosure Statement. Pihlstrom is a review article that discusses the status of diagnosis and treatment of periodontal disease. Dr. Van Dyke declares that Pilstrom's assessment of the treatment plans had not changed between the time of its publication and the filing date of the above-captioned patent application. The Van Dyke Declaration, paragraph 12. Pihlstrom lists several treatment options for periodontal disease. These include systemic treatment, where the

underlying systemic disease causing periodontal disease is targeted; hygienic treatment, where local causes of periodontal disease, including bacterial plaque and calculus are removed, and if necessary, antimicrobial agents, such as minocycline (Arestin®), are administered to kill the bacteria; corrective treatment, where procedures designed to correct the effect of periodontal disease are performed; and maintenance or supportive treatment. The Van Dyke Declaration, paragraph 12; and Pihlstrom, pages 53-55. Applicants note that Pihlstrom does not discuss that anti-inflammatory drugs can be used for the treatment of periodontal disease.

Dr. Van Dyke attributes the absence of anti-inflammatory drugs for the treatment of periodontal disease to the adverse side effects associated with the use of these drugs, whether applied systemically or topically. He lists some adverse events, such as gastrointestinal ulcers and bleeding, bleeding at other tissues, and cardiac episodes, that have been observed with what he calls "troubling frequency" during the use of anti-inflammatory medications. Dr. Van Dyke indicates that "It is generally believed among dentists that the risk of adverse events outweighs the therapeutic benefit of anti-inflammatory drugs." The Van Dyke Declaration, paragraphs 7-9.

Applicants respectfully submit that the general knowledge in the art at the time of the filing of the above-captioned patent application, and in fact even today, taught away from the use of anti-inflammatory drugs for the treatment of periodontal disease. Dentists, who were educated in schools where the use of anti-inflammatory drugs for the treatment of periodontal disease were not taught, and were later further educated by review articles such as Pihlstrom that did not include the use of anti-inflammatory drugs as an option for the treatment of periodontal disease, and were familiar with the adverse side effects of these drugs, would not be motivated to use anti-inflammatory drugs for the treatment of periodontal disease, and would look elsewhere for a viable treatment.

However, because early studies, such Heasman cited above, had suggested that anti-inflammatory drugs could be effective for the treatment of periodontal disease, the dental community has been searching for an anti-inflammatory drug that is effective in the treatment of periodontal disease but does not cause the adverse side effects that has kept the practitioners from using these drugs. Dr. Van Dyke has called this search "elusive" and states that none of the currently available anti-inflammatory drugs meets these requirements. The Van Dyke Declaration, paragraph 14.

Accordingly, Applicants respectfully submit that there is a long felt but unmet need in the art for an effective anti-inflammatory drug for the treatment of periodontal disease, which drug has none of the typical adverse side effects common to other anti-inflammatory drugs. Applicants respectfully submit that the cetylated fatty acids of the present invention meet the need felt in the art. Dr. Van Dyke calls the use of cetyalted fatty acids "a major step forward" and declares that these compounds "provide the requisite anti-inflammatory effect without any adverse side effects." The Van Dyke Declaration, paragraph 15.

Applicants respectfully submit that when all of the factors of *Graham* are considered, including the evidence of secondary considerations, the invention described in the currently pending claims is not obvious in view of the cited references. The present claims are directed to a method of treatment that fills a long felt but unmet need in the art and was taught away by the general knowledge in the art.

Furthermore, Applicants have amended claim 19, the only pending independent claim, to recite specific cetylated fatty acids. Applicants respectfully submit that none of the cited references teach the use of the recited fatty acids for the treatment of periodontal disease. Applicants further submit that none of the cited references suggest the use of the recited fatty acids, or provide the motivation for the use of the recited fatty acids for the treatment of periodontal disease.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejections under 35 U.S.C. § 103.

Rejections under 35 U.S.C. § 112, First Paragraph

Claims 19 and 21-35 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement. The Examiner states that the specification enables a composition comprising lecithin fatty acid, olive oil fatty acid, an esterified fatty acid, and tocophenol, in the stated percentages, but the specification does not enable a composition comprising a cetylated fatty acid. The Examiner states:

> All of the information contained in the specification enables a composition containing lecithin fatty acid, olive oil fatty acid, esterified fatty acid and tocophenol. There is no indication periodontal disease can be treated *only* with a pharmaceutical composition containing *only* cetyl fatty acid. (Emphasis provided.)

The Office Action, page 4, last paragraph. Applicants respectfully traverse.

First, Applicants respectfully submit that the Examiner's statement that "there is no indication periodontal disease can be treated *only* with" the disclosed compositions is a conclusion reached by an erroneous reading of the specification. Applicants have never stated, and the specification does not teach, that the disclosed compositions and methods of treatment are the *only* methods of treatment for periodontal disease available to the patients. Applicants are naturally very familiar with the state of the art of treatment for periodontal disease. Applicants know that there are currently available treatments for various stages of periodontal disease in the market, including brushing, flossing, aggressive cleaning, and medications such as minocycline (ARESTIN®) and doxycycline hyclate (PERIOSTAT®). Applicants respectfully submit that the specification does disclose various available therapies for periodontal disease, for example at page 19, last line to page 20, last line. Applicants respectfully submit that the currently available treatments leave an unfilled gap and that the compositions and methods disclosed in the specification provide an additional, and powerful, tool for the practitioner to combat this disease. Therefore, the specification does not indicate that the disclosed methods are the *only* available methods of treating periodontal disease.

Next, the Examiner alleges that the present claims are directed to treating periodontal disease with a composition containing *only* cetylated fatty acid. The text of the independent claim before the Examiner at the time this rejection was made read:

> 19. A method of treating periodontal disease comprising administering an effective amount of a composition *comprising* a cetylated fatty acid to a subject in need of such treatment. (Emphasis provided.)

The second instance of the word "comprising" in claim 19 modifies the word "composition," meaning that the composition to be administered *comprises* a cetylated fatty acid.

It is well established that the word "comprising" is an open ended transition word. The MPEP summarizes the holdings of various courts by stating:

> The transitional term "comprising" . . . is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. . . . *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "*the claim open for the inclusion of unspecified ingredients even in major amounts*"). (Emphasis provided. Various citations omitted.)

MPEP 2111.03. Therefore, claim 19 is directed to administering a composition that comprises, or has, a cetylated fatty acid, but can also have other ingredients.

The Examiner has correctly determined that "the specification enables a composition containing lecithin fatty acid, olive oil fatty acid, esterified fatty acid and tocophenol." Therefore, Applicants respectfully submit that the Examiner's own statement supports the position that the specification is enabling for a composition *comprising* a cetylated fatty acid.

In addition, Applicants respectfully submit that the specification makes quite clear that the pharmaceutically active ingredient in the compositions that are administered to the patient for the treatment of periodontal disease is a cetylated fatty acid. For example, the specification states in Example 6 that:

> The results of this study will be used to understand the local effects of cetylated fatty acids on the gingival tissues and periodontal disease progression. The specification, page 37, lines 2-4.
>
> The potential effects of the monosaturated fatty acid complex (cetylated fatty acids) in the prevention of the periodontal inflammation induced by the periodontitis-specific microorganism P. gingivalis will be studied. The specification, page 38, lines 9-11.

The specification, therefore, discloses that the cetylated fatty acids are the active pharmaceutical ingredients.

The specification also states that the disclosed compositions can comprise additional ingredients served as excipients or carriers. For example, the specification states:

> The pharmaceutical composition may further comprises biocompatable [sic] polymers as protective colloids, suspensions or bulking agents, excipients, binders and carriers, as appropriate.

The specification, page 4, lines 19-21. Applicants respectfully submit that the additional ingredients that the Examiner has listed, i.e., lecithin fatty acid, olive oil fatty acid, and tocophenol, are known in the art to be excipients or carriers.

Therefore, Applicants respectfully submit that the specification has fully enabled a method of treating periodontal disease by administering a composition that comprises the pharmaceutically active ingredient by providing the procedure for such administration. The claims need not recite the additional ingredients that are not therapeutically active. To further clarify that the compositions used in the methods claimed herein do comprise additional

ingredients than just the cetylated fatty acids, Applicants have amended the claims to include at least one of the recited excipients and carriers as well.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejections under 35 U.S.C. § 112, first paragraph.

CONCLUSION

Applicants have amended claim 19 and have added new claims 37-48. No claim is cancelled. Accordingly, claims 19, 21-35, and 37-48 are pending.

Applicants have endeavored to respond to all of the Examiner's objections and rejections set forth in the Office Action of October 22, 2007. Applicants respectfully submit that the claims as amended herewith are patentable and request a notice to that effect.

No fee is believed due in connection with this response. Applicants invite the Examiner to call the undersigned if any issue can be resolved through a telephonic discussion.

Respectfully submitted,

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